

**REMARKS**

Claims 19-28, 32-34 and 41-48 are pending in this Application. By this Amendment, non-elected Claims 1-18, 29-31, and 35-40 are canceled without prejudice or disclaimer, Claims 19, 21, 23, 27 and 34 are amended and Claims 41-48 are added. Support for new Claims 41-48 can be found in the specification, including the original claims and figures, for example, see paragraph 54 and Figures 1-4. Reconsideration in view of the above amendments and following remarks is respectfully requested.

**I. 35 U.S.C. §102(b)**

The Office Action rejects Claims 19-22, 24-27, and 32-33 under 35 U.S.C. §102(b) over Howell et al. (U.S. Patent No. 5,743,251, hereinafter "Howell"). Because Howell fails to disclose or suggest all the features of the claims, the rejection is respectfully traversed.

The Office Action states on page 3, first paragraph, that the aerosol confinement sleeve of the claimed invention is broadly interpreted to be Howell's mouthpiece 39. However, Applicants respectfully submit that Howell does not disclose or suggest, the combination of features recited in Claim 19, which includes at least the feature of an aerosol confinement sleeve having a length and/or a largest transverse dimension to achieve a desired size of aerosol particle of the aerosol. Rather, Howell states that "the mouthpiece 39 is disposed proximate the open 25 of the tube and facilitates complete mixing of the volatilized material with cooler ambient air such that the volatilized material condenses to form particles." See Howell, column 6, lines 32-47.

Furthermore, Howell states that "[m]anipulation of parameters of the aerosol generator such as the internal diameter of the tube, heat transfer characteristics of the tube, heating capacity of the heater, and the rate at which material in liquid form is supplied to the tube are presently expected to affect aerosol temperature and mass median particle diameter." See Howell column 9, lines 22-32. As such, Howell fails to disclose or suggest utilizing an aerosol confinement sleeve having a length and/or a largest transverse dimension to affect the mass median particle diameters of an aerosol.

Additionally, Applicants respectfully submit that Howell does not disclose or suggest, the combination of features recited in Claim 27 (rewritten in independent form), which includes at least the feature of an aerosol confinement sleeve has a length of from about 1/4 inch to about 4 inches, a largest transverse dimension of from about 1/4 inch to about 2 inches, and a ratio of the largest transverse dimension to the length thereof of from about 1:1 to about 0.25:4.

For at least the reasons set forth above, Applicants respectfully submit that Claims 19 and 27 are allowable. Claims 20-22, 24-26, and 32-33 depend from Claim 19, and are allowable for at least the same reasons. Withdrawal of the rejection is respectfully requested.

## **II. 35 U.S.C. §103(a)**

The Office Action rejects Claims 23, 28, and 34 under 35 U.S.C. §103(a) over Howell in view of Armer et al. (U.S. Patent No. 5,954,047, hereinafter "Armer"). Since Howell and Armer, alone or in combination, fail to disclose or suggest all the features of the claims, the rejection is respectfully traversed.

For at least the reasons set forth above, Applicants respectfully submit that Howell fails to disclose or suggest the features of Claim 19 from which Claims 23 and 28 depend. Armer fails to cure the deficiencies of Howell. Additionally, with respect to Claim 34, Applicants respectfully submit that Howell does not disclose or suggest, the combination of features recited in Claim 34, which includes at least the features of heating the liquid so as to volatilize liquid in the flow passage, and a body surrounding a portion of a flow passage such that a space is defined between a capillary passage and the body, the aerosol confinement sleeve being attached to the body, the body having a first inner diameter and the aerosol confinement sleeve having a second inner diameter, wherein (i) the first inner diameter is approximately equal to the second inner diameter, or (ii) the first inner diameter is smaller than the second inner diameter.

With respect to Claim 34, Applicants respectfully submit that Armer discloses a metered dose inhaler which includes a housing defining a conduit with a mouthpiece, and an actuator with a nozzle discharge orifice arranged to discharge aerosol to the conduit. See Armer Abstract. However, Armer fails to disclose or suggest at least the features of heating a liquid so as to volatilize the liquid in a flow passage and admixing the volatilized liquid with air to produce an aerosol, wherein the flow passage is a capillary passage and a body surrounds a portion of the flow passage such that a space is defined between the capillary passage and the body, the aerosol confinement sleeve being attached to the body, the body having a first inner diameter and the aerosol confinement sleeve having a second inner diameter, wherein (i) the first inner diameter is approximately equal to the second inner

diameter, or (ii) the first inner diameter is smaller than the second inner diameter, as well as the combination of features.

The Office Action states:

it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Howell et al. by altering the metered dose inhaler of the prior art to have a body structure with an inner diameter equal to that of the confinement sleeve and a removable mouthpiece and to dispense anti-inflammatory medicaments because it is well known in the art, as taught by Armer et al., to dispense anti-inflammatory agents through a metered dose inhaler with a body of equal diameter of a confinement sleeve in order to dispense the medication and to use a removable confinement sleeve so that different patients can use the same inhaler apparatus or the confinement sleeve can be disinfected before the user dispensing the medication again.

See the Office Action, pages 4 and 5.

As mentioned above, Armer clearly does not disclose or suggest heating a liquid so as to volatilize the liquid in a flow passage. Rather, Armer discloses "enhanced mixing of the aerosol with air, which promotes more complete evaporation of liquid propellant ... [a]ccordingly, a greater fraction of the metered dose of medication dispensed from the canister 18 exits the open end 20 in the form of respirable dry particles of the optimum size of about one to five microns moving at a relatively low velocity that substantially matches the inspiratory breath velocity." See Armer column 7, lines 4-16. Armer and Howell, alone or in combination, therefore do not disclose or suggest the combination of features recited in Claim 34 which includes admixing volatilized liquid with air to produce an aerosol, wherein a flow passage is a capillary passage and a body surrounds a portion of the flow passage such that a space is defined between the capillary passage and the body, the aerosol confinement sleeve being attached to the body, the body having a first inner diameter and the aerosol confinement sleeve having a second inner diameter,

wherein (i) the first inner diameter is approximately equal to the second inner diameter, or (ii) the first inner diameter is smaller than the second inner diameter; and heating the liquid so as to volatilize liquid in the flow passage.

For at least the reasons set forth above, Applicants respectfully submit that Howell and Armer fail to disclose or suggest all the features recited in Claim 34. Applicants submit that Claims 23 and 28 are allowable for at least the same reasons as Claim 19. Withdrawal of the rejection is respectfully requested.

**III. New Claims**

Claims 41-48 are added to the application. Applicants respectfully submit that all pending claims are in condition for allowance.

**CONCLUSION**

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned be contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

Respectfully submitted,

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